

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

MERCK SHARP & DOHME LLC,

Plaintiff,

v.

GLAND PHARMA LIMITED,

Defendant.

No. 22 CV 5461 (JXN)(ESK)

JOINT PROPOSED DISCOVERY PLAN

Pursuant to Federal Rules of Civil Procedure 16 and 26(f) and Local Civil Rule 26.1(b) Plaintiff Merck Sharp & Dohme LLC (“Merck” or “Plaintiff”) and Defendant Gland Pharma Limited (“Gland” or “Defendant”) have conferred and submit the following Joint Proposed Discovery Plan.

1. Set forth a factual description of the case. Include the causes of action and affirmative defenses asserted.

Joint Response: This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, et seq., filed by Merck in response to Gland’s filing of Abbreviated New Drug Application (“ANDA”) No. 217553 with the United States Food and Drug Administration (“FDA”). Gland is seeking approval from the FDA to commercially market generic versions of Merck’s NOXAFIL® (posaconazole) intravenous (infusion) solution, 300 mg/16.7 mL (18 mg/mL) drug product (“Gland’s ANDA Product”) before the expiration of United States Patent Nos. 9,023,790 (the “790 Patent”) and 9,358,297 (the “297 Patent”).

In this litigation, Merck asserts that Gland’s ANDA filing constitutes infringement of one or more claims of the patents-in-suit, and that Gland’s ANDA Products will infringe those claims after FDA approval. Gland asserts that the patents-in-suit are invalid and/or not infringed.

2. Have settlement discussions taken place?

Joint Response: Yes.

3. Have the parties exchanged the information required by Fed. R. Civ. P. 26(a)(1)? If not, state the reason therefor.

Joint Response: No. The parties’ proposed date for Rule 26(a)(1) disclosures are set forth in the schedule in **Exhibit A**.

4. Describe any discovery conducted other than the above disclosures.

Joint Response: On March 6, 2023, Gland produced a copy of ANDA No. 217553 pursuant to L. Pat. R. 3.6(a). No other discovery has been conducted to date.

5. Generally, dispositive Motions cannot be filed until the completion of discovery. Describe any Motions any party may seek to make prior to the completion of discovery. Include any jurisdictional Motions and Motions to Amend.

Joint Response: The parties submit that dispositive motions are inappropriate in this case until the completion of discovery.

6. The parties proposed the following:

a. Discovery is needed on the following subjects:

Joint Response: Discovery relating to the claims and defenses in the parties' pleadings, including infringement and validity of the patents-in-suit, as well as various related issues, claims, and affirmative defenses.

b. Should discovery be conducted in phases? If so, explain.

Joint Response: Discovery should not be conducted in phases.

c. Number of Interrogatories by each party to each other party:

Joint Response: The Federal Rules of Civil Procedure provide a sufficient starting point for the number of Interrogatories served by each side. Accordingly, the parties provisionally agree that each side be allowed to serve up to 25 Interrogatories, which shall be responded to by 30 days from the date of receipt. Should the need arise, the parties can discuss the possibility of additional Interrogatories in the future and will see the Court's permission accordingly.

d. Number of Depositions to be taken by each party:

Joint Response: The Federal Rules of Civil Procedure provide a sufficient starting point for the number of depositions taken by each side. Accordingly, no change to Fed. R. Civ. P. 30(a)(2)(A)(i) regarding depositions is requested. Should the need arise, the parties can discuss the possibility of additional depositions in the future.

e. Plaintiff's expert report

Joint Response: The parties' proposed schedule is attached hereto as **Exhibit A**.

f. Defendant's expert report

Joint Response: The parties' proposed schedule is attached hereto as **Exhibit A**.

g. Motions to Amend or to Add Parties

Joint Response: The parties' proposed schedule is attached hereto as **Exhibit A**.

h. Deadline for serving dispositive motions

Joint Response: The parties' proposed schedule is attached hereto as **Exhibit A**.

i. Completion of factual discovery

Joint Response: The parties' proposed schedule is attached hereto as **Exhibit A**.

j. Completion of expert discovery

Joint Response: The parties' proposed schedule is attached hereto as **Exhibit A**.

k. Set forth any special discovery mechanism or procedure requested, including data preservation orders or protective orders:

Plaintiff's Response: Due to the fact Gland is a foreign entity organized and existing under the laws of India, international discovery, including potentially pursuant to the Hague Convention or other international authority, may be required. The parties agree that foreign defendant Gland will make reasonable efforts to bring all foreign witnesses to the United States for deposition. If after reasonable efforts witnesses are unable to travel to the United States due to the current global health crisis, Gland agrees to confer in good faith to identify alternative locations and/or means of making available foreign witness for deposition. Additional time for discovery may be required if Defendant is unable to timely do so. Relatedly, documents may require translations. The parties are to produce translations of any produced documents in a foreign language.

Furthermore, the parties agree that they will use best efforts to agree to mutually convenient dates, locations, and methods (e.g., by video or other appropriate remote deposition technology if necessary) for depositions noticed by either side. A party may choose to notice a deposition by remote means, however, a party's decision to take a deposition remotely shall not preclude another party from defending the deposition in person.

Defendants' Response:

Due to the fact Gland is a foreign entity organized and existing under the laws of India, international discovery, including potentially pursuant to the Hague Convention or other international authority, may be required. The parties agree that foreign defendant Gland will make reasonable efforts to bring all foreign witnesses under Gland's control to the United States for deposition. If after reasonable efforts witnesses are unable to travel to the United States due to the current global health crisis, Gland agrees to confer in good faith to identify alternative locations and/or means of making available foreign witness under its control for deposition. Additional time for discovery may be required if Defendant is unable to timely do so. Relatedly, documents may require translations. The parties are to produce translations of any produced documents in a foreign

language if a translation exists within the documents collected through the discovery process. Neither party is under an obligation to create translations of documents as part of this litigation.

Furthermore, the parties agree that they will use best efforts to agree to mutually convenient dates, locations, and methods (e.g., by video or other appropriate remote deposition technology if necessary) for depositions noticed by either side. A party may choose to notice a deposition by remote means.

l. A pretrial conference

Joint Response: The parties' proposed schedule is attached hereto as **Exhibit A**.

m. Trial by jury or non-jury Trial?

Joint Response: Non-Jury trial.

n. Trial date:

Joint Response: The parties' proposed schedule is attached hereto as **Exhibit A**.

7. Do you anticipate any discovery problem(s)? If so, explain.

Joint Response: No, but see Section 6(k), above.

8. Do you anticipate any special discovery needs (i.e., videotape/telephone depositions, problem with out-of-state witnesses or documents, etc.)?

Joint Response: No, but see Section 6(k), above.

9. State whether this case is appropriate for voluntary arbitration (pursuant to L. Civ. R. 201.1 or otherwise), mediation (pursuant to L. Civ. R. 301.1 or otherwise), appointment of a special master or other special procedure. If not, explain why and state whether any such procedure may be appropriate at a later time (i.e., after exchange of pretrial disclosures, after completion of depositions, after disposition of dispositive motions, etc.).

Joint Response: The parties do not believe that this case is appropriate for voluntary arbitration, mediation, appointment of a special master, or other special procedure at this time.

10. Is this case appropriate for bifurcation?

Joint Response: No.

11. Do the parties consent to the trial being conducted by a Magistrate Judge.

Joint Response: No.

12. Pursuant to Local Patent Rule 2.1(a), the parties report the following from the 26(f) conference:

- a. Proposed modification of the obligations or deadlines set forth in these Local Patent Rules to ensure that they are suitable for the circumstances of the particular case (see L. Pat. R. 1.3)**

Joint Response: The parties have addressed this issue in the proposed schedule attached hereto as **Exhibit A**.

- b. The scope and timing of any claim construction discovery including disclosure of and discovery from any expert witness permitted by the Court.**

Joint Response: The parties have addressed this issue in the proposed schedule attached hereto as **Exhibit A**.

- c. The format of the Claim Construction Hearing, including whether the Court will hear live testimony, the order of presentation, and the estimated length of the hearing.**

Joint Response: The parties will submit this information in the Joint Claim Construction and Prehearing Statement and refer the Court to **Exhibit A** for the parties' proposed date for submission of the joint statement.

- d. How the parties intend to educate the Court on the patent(s) at issue.**

Joint Response: The parties intend to educate the Court on the patents at issue through at least submissions to the Court, which may include Markman tutorial(s).

- e. The need for any discovery confidentiality order and a schedule for presenting certification(s) required by L. Civ. R. 5.3(b)(2).**

Joint Response: The parties will submit a proposed Discovery Confidentiality Order and refer the Court to **Exhibit A** for their proposed due date for submission of the order.

- f. Other information required by Local Patent Rule 2.1(a)**

- i. The availability and timing of production of invention records (including inventor laboratory notebooks and analytical test results).**

Plaintiff's Response: Merck's investigation regarding the availability and timing of production of invention records is ongoing.

- ii. The availability and timing of production of ANDA product research and development documents.**

Defendant's Response: Gland's investigation into the availability and timing of production of ANDA product research and development documents is ongoing.

iii. The availability and timing of production of ANDA product samples.

Plaintiff's Response: Merck emphasizes the importance of early production of samples of the accused instrumentality, including, but not limited to, Gland's ANDA Product. Merck trusts that Gland will make good-faith efforts to ensure the timely production of samples to Merck and Merck will promptly raise any issues with the Court should the need arise.

Defendant's Response: The production of samples is not critical to this litigation, as the claim limitations are directed to parameters described in the ANDA itself. As such, testing of Gland's ANDA Product will not materially affect Merck's ability to pursue its claims of infringement. Additionally, Gland's ability to produce samples may be limited by FDA regulations or import restrictions outside its control. However, Gland will make a good-faith effort to secure samples of its ANDA Product for production.

iv. The date of conception and the date of reduction to practice for each patent asserted in the action, if applicable.

Plaintiff's Response: Merck will provide the information required by the Local Patent Rules with its contentions.

v. Each inventor's availability for deposition in the matter.

Plaintiff's Response: None of the named inventors of the patents-in-suit are current employees of Plaintiff. Plaintiff will confer with Defendants regarding their availability and location for deposition at an appropriate juncture in the fact discovery period.

vi. Availability of foreign witnesses for deposition and foreign documents.

Plaintiffs' Response: Merck is currently unaware of any foreign witnesses or foreign documents of its own. All Merck's dates and other proposals herein assume that Gland will make available any foreign witnesses in the United States for deposition and will produce any documents located in India to Merck in the United States. *See supra*, Section 6(k). Additional time for discovery and/or motion practice may be required if Defendant is unable to timely do so.

Defendants' Response: Gland is a foreign company, and so its documents and witnesses are in India. Gland will take appropriate steps to comply with document discovery within the United States. As discussed above in Section 6(k), the availability of foreign witnesses under Gland's control within the United States is outside Gland's power. Gland will make good-faith efforts to have its witnesses made available for deposition, either in-person or remotely, within the fact discovery period.

vii. Whether there is a 30-month stay and if so, when it ends.

Joint Response: February 1, 2025.

viii. A date for substantial completion of document production and a method for determining compliance.

Joint Response: The parties' proposed schedule is attached hereto as **Exhibit A**.

ix. **Any other issues or matters that a party believes are time sensitive.**

Joint Response: None.

Date: March 10, 2023

/s/ James S. Richter

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EXHIBIT A

Event	Proposed Dates
Exchange Rule 26(a)(1) Initial Disclosures	3/14/2023
Initial Scheduling Conference	3/15/2023
Plaintiff identifies asserted claims pursuant to L. Pat. R. 3.6(b)	4/21/2023
Parties submit proposed Discovery Confidentiality Order	4/28/2023
Defendant serves Invalidity Contentions and Non-Infringement Contentions of asserted claims with supporting documents pursuant to L. Pat. R. 3.6(c)-(f)	5/15/2023
Plaintiff serves Infringement Contentions and Responses to Invalidity Contentions with supporting documents pursuant to L. Pat. R. 3.6(g)-(i)	6/29/2023
Parties exchange proposed terms for construction and thereafter meet and confer to narrow issues pursuant to L. Pat. R. 4.1(a)	7/13/2023
Parties exchange preliminary proposed constructions and identifications of intrinsic and extrinsic evidence and thereafter meet and confer to narrow issues pursuant to L. Pat. R. 4.2(a)-(b)	8/3/2023
Parties exchange evidence opposing proposed claim constructions and thereafter meet and confer to narrow issues pursuant to L. Pat. R. 4.2(c)	8/17/2023
Joint Claim Construction and Prehearing Statement pursuant to L. Pat. R. 4.3	9/3/2023
Completion of fact discovery related to claim construction pursuant to L. Pat. R. 4.4	10/3/2023
Parties file opening <i>Markman</i> briefs with supporting evidence including expert declarations and certifications pursuant to L. Pat. R. 4.5(a)	10/18/2023
Completion of expert discovery regarding <i>Markman</i> issues pursuant to L. Pat. R. 4.5(b)	11/17/2023
Parties file responsive <i>Markman</i> briefs with supporting evidence pursuant to L. Pat. R. 4.5(c)	12/18/2023
Amendments to the pleadings or to join other parties with leave of Court	12/20/2023
Parties propose schedule to the Court for Claim Construction Hearing pursuant to L. Pat. R. 4.6	1/2/2024
Markman Hearing	To be determined
Substantial completion of document production	February 7, 2024
Status Conference with Court	Late February, 2024
Close of fact discovery	To be determined

Opening expert reports on issues for which the party bears the burden of proof	60 days from close of fact discovery
Rebuttal expert report (Plaintiff's rebuttal expert reports shall include any disclosure regarding secondary considerations)	45 days from opening expert reports
Reply expert reports (including, but not limited to Defendants' response regarding secondary considerations)	30 days from rebuttal expert reports
Close of expert discovery	45 days from rebuttal expert reports
Deadline for Filing Dispositive Motions	To be determined
Deadline for Filing Pretrial Order	To be determined
Pretrial Conference	To be determined
Bench Trial	To be determined
30-Month Stay Ends	February 1, 2025